

Claims

1. (Previously presented) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

2. (Previously presented) A closure system according to claim 1 wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the sealing ridge being detachable from the clamp part.

3. (Cancelled)

4. (Previously presented) A closure system according to claim 1 wherein said frangible link is linked to the skirt wall of the cover part.

5. (Previously presented) A closure system according to claim 1 further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

6. (Previously presented) A closure system according to claim 5 wherein the clamp part comprises:

- an upper wall having the aperture therein,
- a peripheral skirt wall extending downwardly from said upper wall, and
- snap-fit engagement parts to engage with the vial,

and where said upper wall and the upwardly convex part of the closure part are profiled such that the upwardly convex part bulges above the adjacent upper surface of the upper wall.

7. (Previously presented) A closure system according to claim 6 wherein said upper surface of the clamp part and the upwardly convex part of the closure part are profiled to form a smooth convex shape.

8. (Previously presented) A closure system according to claim 1 wherein the upper surface of the closure part adjacent to the said region is made of a thermoplastic elastomer material.

9. (Previously presented) A closure system according to claim 1 characterized in that the clamp part is made of a moldable plastics material and is engageable with the rim bounding the mouth opening of the vial.

10. (Previously presented) A pharmaceutical vial having an upwardly facing mouth opening closed by a closure system comprising:

- an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

11. (Previously presented) A method of closing a vial having an upwardly-facing mouth opening bounded by a rim in the form of a flange having upper and lower surfaces extending transverse to its upper-lower axis, comprising

inserting into the mouth opening an elastomer closure part shaped to sealingly engage with the mouth opening, and having a lower surface to face the interior of the vial and an opposite upper surface to face away from the vial, and capable of being punctured by a needle,

providing a clamp part able to engage with the flange around the rim of the mouth opening of the vial by a resilient snap-fit engagement of a snap fit part of the clamp part underneath a downwardly facing surface of such a flange part, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening,

engaging the clamp part with the assembly of vial and closure part by said snap-fit engagement,

providing a cover part comprising an upper wall and a peripheral skirt wall, said cover part being engageable with the clamp part by means of a snap-fit between the clamp part and the skirt wall, wherein when so engaged said cover part covers the closure part and a lower surface of the cover part faces the upper surface of the closure part and

engaging the cover part with the clamp part by said snap-fit.

12. (Previously presented) A method of filling a pharmaceutical vial having an upwardly-facing mouth opening, comprising the steps of:

providing an assembly of an empty vial having an elastomer closure part shaped to sealingly engage with the mouth opening and having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle, and a clamp part engaged with the vial, and bearing upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial;

inserting a filling needle downwardly through the region of the upper wall of the closure part;

injecting a liquid medicament through the filling needle into the vial;

withdrawing the needle to leave a residual puncture hole;

engaging a cover part with the clamp part to cover the said region of the closure part by means of a snap-fit between a peripheral skirt wall of the cover part and the clamp part.

13. (Previously presented) A method according to claim 12 further comprising, prior to engaging the said cover part, directing a source of heat at the residual puncture hole in the upper surface of the closure part to melt the elastomer material in the immediate locality of the puncture, and to thereby seal the residual puncture hole.

14. (Currently amended) A pharmaceutical vial and a closure for closing said vial, wherein the vial has an upwardly facing mouth opening and neck, and wherein the closure comprises a plug part which has an outward-facing neck-contacting surface which is cylindrical adjacent the lower end of the plug part, and which engages with the interior surface of the vial neck in such a manner as to be against the interior surface of the vial neck when the closure is in place is against the cylindrical interior surface of the vial neck, said plug part further comprising an interior-facing surface which is exposed to the interior of the vial and an upper part which is suitable for being punctured by a needle, wherein the interior-facing surface-encloses, immediately below the plug part, an angle of 120-160° with the interior surface of the vial neck,

further wherein the outward-facing neck-contacting surface and the interior-facing surface of the plug part form an edge enclosing an angle of less than 90° between them and having a radius of curvature of 0.5 mm or less, and wherein the vial neck has a conical profile such that the vial neck is wider at its mouth opening than at a point adjacent the lower end of the plug part.

15. (Previously presented) A vial closure according to claim 14 wherein the angle is 135° +/-10°.

16. (Canceled).

17. (Previously presented) A pharmaceutical vial according to claim 10 retained in a stand, where said stand comprises:

a ring-shaped body having an inner perimeter adapted to engage with the base of the vial;
and

an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein,

wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.